CHAPTER 16
NUCLEAR PHARMACY PRACTICE

[Prior to 12/14/88, see Pharmacy Examiners Board 657—8.8(155A)]

657—16.1(155A) Purpose and scope. It is unlawful to receive, possess or transfer radioactive drugs except in accordance with the provisions of Iowa Code chapter 155A. It is also unlawful for any person to provide radiopharmaceutical services unless the person is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with the provisions of Iowa Code chapter 155A, board rules and rules of the environmental protection commission. It is not unlawful for a medical practitioner to receive, possess, or transfer radioactive drugs for administration to patients as provided in Iowa Code chapter 148. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions set forth by the environmental protection commission pursuant to the provisions of Iowa Code chapter 455B. The requirements of these nuclear pharmacy rules are in addition to and not in substitution for 657—Chapter 8 and other applicable provisions of rules of the board and the environmental protection commission or the public health department.

657—16.2(155A) Definitions.

"Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

"Board" means the Iowa board of pharmacy examiners.

"Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"Qualified nuclear pharmacist" means a person currently licensed to practice pharmacy in Iowa who meets the qualifications established by rule 16.3(155A).

"Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine the radiopharmaceuticals' suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

"Radiopharmaceutical service" means, but is not limited to, the preparation, dispensing, labeling and delivery of radiopharmaceuticals; the compounding of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, as necessary or required, of the therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

657—16.3(155A) General requirements for qualified nuclear pharmacist. A qualified nuclear pharmacist shall meet all requirements of either alternative one or alternative two established in subrules 16.3(1) and 16.3(2), respectively.

16.3(1) *Alternative one.* A qualified nuclear pharmacist shall:

a. Meet minimum standards of training for medical uses of radioactive materials; and

b. Be a currently licensed pharmacist in the state of Iowa; and

c. Submit an affidavit of experience and training to the board; and

d. Have completed one of the following nuclear pharmacy training alternatives:

(1) Received a minimum of 90 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy. In addition, the pharmacist shall have attained a minimum of 160 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy that provides nuclear pharmacy services or in a structured clinical nuclear pharmacy training program of an accredited college of pharmacy.

(2) Successfully completed a nuclear pharmacy residency accredited by the American Society of Health-System Pharmacists (ASHP).

(3) Successfully completed a certificate program in nuclear pharmacy accredited by the American Council on Pharmaceutical Education (ACPE).

16.3(2) *Alternative two.* A qualified nuclear pharmacist shall:

a. Be a currently licensed pharmacist in the state of Iowa; and

b. Be certified by the Board of Pharmaceutical Specialties as a board-certified nuclear pharmacist (BCNP); and

c. Submit an affidavit of BCNP credentials to the board.

657—16.4(155A) General requirements for pharmacies providing radiopharmaceutical services.

16.4(1) *Qualified nuclear pharmacist.* A license to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist who shall be the pharmacist in charge of the pharmacy. The pharmacist in charge shall be responsible for, at a minimum, the requirements in rule 657—6.2(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist is responsible for all operations of the pharmacy and, except in emergency situations, shall be in personal attendance at all times that the pharmacy is open for business.

16.4(2) *Space requirements.* Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office areas.

16.4(3) *Personnel appropriately trained.* The pharmacist in charge shall be responsible for ensuring that all pharmacy personnel have been appropriately and adequately trained for their assigned tasks.

16.4(4) *Records required.* Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules of the board and the environmental protection commission.

16.4(5) *Compliance with laws.* Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

16.4(6) *Prescription and office use.* Radioactive drugs shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals to practitioners for office use.

16.4(7) *Outer-container label.* In addition to any of the board's labeling requirements for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

a. The standard radiation symbol;
b. The words "Caution — Radioactive Material";
c. The name of the radionuclide;
d. The chemical form;
e. The amount of radioactive material contained, in millicuries or microcuries;
f. If the radioactive drug is a liquid, the volume in cubic centimeters;
g. The requested calibration time for the amount of radioactivity contained.

16.4(8) *Immediate-container label.* The immediate container shall be labeled with:

a. The standard radiation symbol;
b. The words "Caution — Radioactive Material";
c. The name of the pharmacy; and
d. The prescription number.

16.4(9) *Radioactivity.* The amount of radioactivity for each individual preparation shall be determined by radiometric methods immediately prior to dispensing.

16.4(10) *Redistribution.* A nuclear pharmacy may redistribute to another nuclear pharmacy or authorized party radioactive drugs that are the subject of an approved new drug application if the pharmacy does not process the radioactive drugs in any manner or violate the product packaging.

657—16.5(155A) Library. Each nuclear pharmacy shall have access to the following references. References may be printed or computer-accessed and shall be current editions or revisions.

1. United States Pharmacopoeia/National Formulary, with supplements;
2. The Iowa Pharmacy Law and Information Manual;
3. State rules and federal regulations governing the use of applicable radioactive materials;
4. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—16.6(155A) Minimum equipment requirements. Each nuclear pharmacy shall maintain the following equipment for use in the provision of radiopharmaceutical services:

1. Laminar flow hood;
2. Dose calibrator;
3. Refrigerator;
4. Single-channel scintillation counter;
5. Microscope;
6. Autoclave, or access to one;
7. Incubator, or access to one;
8. Radiation survey meter;
9. Other equipment necessary for the radiopharmaceutical services provided as required by the board.

A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—Chapter 34.

These rules are intended to implement Iowa Code sections 155A.4, 155A.13, 155A.28, and 155A.31.

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